UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC. and ALLERGAN INDUSTRIE, SAS, **Plaintiffs,** **v.** **MEDICIS AESTHETICS, INC., et al.** **Defendants.**	**CASE NO. SACV 13-1436 AG (JPRx)** **CLAIM CONSTRUCTION ORDER**

BACKGROUND

Plaintiffs Allergan USA, Inc. and Allergan Industrie, SAS ("Plaintiffs") own or exclusively license United States Patent Nos. 8,450,475 ("'475 Patent") and 8,357,795 ("'795 Patent"). The patents claim injectable soft tissue fillers used to compensate for the effects of aging, and methods of preparing such fillers. Plaintiffs allege that Defendants Medicis Aesthetics, Inc., Medicis Pharmaceutical Corporation, Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals International, Inc. ("Defendants") infringe both patents. The parties dispute the meaning of three groups of claim terms and have agreed to the meaning of seven claim terms. (Jt. Claim Construction and Prehearing Statement, Dkt. No. 52.)

LEGAL STANDARD

Claim construction is an interpretive issue "exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). It begins with an analysis of the claim language itself, *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001), since the claims define the scope of the patent right. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). In construing the claim language, the Court begins with the principle that "the words of a claim are generally given their ordinary and customary meaning." *Id*. (internal quotation marks omitted).

"The ordinary and customary meaning is the meaning that the [claim] term would have to a person of ordinary skill in the art in question at the time of the invention." *Id*. at 1313. "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* Where the patent itself does not make clear the meaning of a claim term, courts may look to "those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean," including the

prosecution history and "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id*. at 1314.

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id*. "In such circumstances general purpose dictionaries may be helpful." *Id*. In other cases, claim terms will not be given their ordinary meaning because the specification defines the term to mean something else. *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1334 (Fed. Cir. 2004); *Kumar v. Ovonic Battery Co., Inc.*, 351 F.3d 1364, 1368 (Fed. Cir. 2003). For the specification to define a term to mean something other than its ordinary meaning, it must set out its definition in a manner sufficient to provide notice of that meaning to a person of ordinary skill in the art. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

ANALYSIS

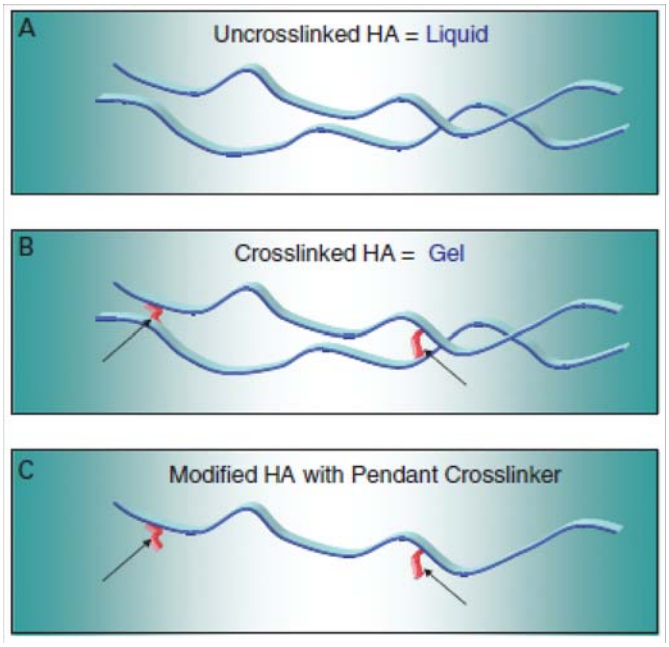
1. TECHNOLOGY OVERVIEW

For its understanding of the technology at issue, the Court relies on the intrinsic and extrinsic evidence submitted by the parties. Both patents relate to "injectable soft tissue fillers" and more specifically to "hyaluronic acid-based dermal and subdermal fillers including an anesthetic agent." ('475 Patent 1:16-19; '795 Patent 1:16-19.) Such fillers are injected into the face to temporarily fill wrinkles and lines that result from aging and environmental factors. ('475 Patent 1:23-34.) Ideally, fillers should cause minimal discomfort upon injection, be long-lasting to require fewer injections, and not induce allergic responses. ('475 Patent 1:35-41.) The FDA regulates fillers as medical devices. (*See* '475 Patent 1:42-45, 54-65.)

Today, many dermal fillers use hyaluronic acid ("HA") as a base. (Kablik et al., *Comparative Physical Properties of Hyaluronic Acid Dermal Fillers*, 35 Dermatol. Surg. 302

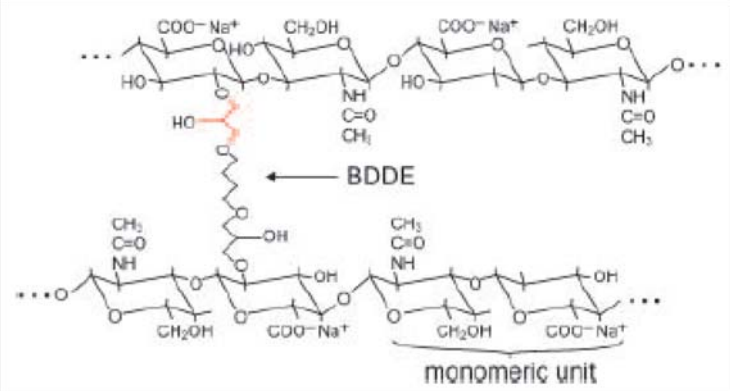
(2009) ("Kablik"), Decl. of Elizabeth Flanagan in Supp. of Pls.' Responsive Claim Construction Br., Dkt. No. 65-1, Ex. G 302.) HA is a water soluble polysaccharide made by the body that can bind to large amounts of water, adding volume to soft tissue such as skin. ('475 Patent 1:66-2:6; Kablik 303.) HA also does not induce allergic responses, making it an excellent candidate for filler use. ('475 Patent 2:2-6; Tezel and Fredrickson, *The science of hyaluronic acid dermal fillers*, 10 J. Cosmetic and Laser Therapy 35 (2008) ("Tezel"), Decl. of William F. Cavanaugh in Supp. of Defs.' Claim Construction Br. ("Cavanaugh Decl."), Ex. 1, Dkt. No. 54-1 36.)

But in its natural state, HA degrades rapidly once injected, requiring frequent injections to keep wrinkles at bay. (Kablik 303-04; Tezel 37.) One way to address this problem is to link HA polymers—chains of HA—together using a chemical compound called a crosslinking agent. ('475 Patent 2:15-19; Tezel 37.) As shown in the below figure, when uncrosslinked HA (image A) reacts with a crosslinking agent, the crosslinking agent may connect to one HA strand by bonding on one end and forming a pendant group (image C), or to two HA strands, linking them (image B):



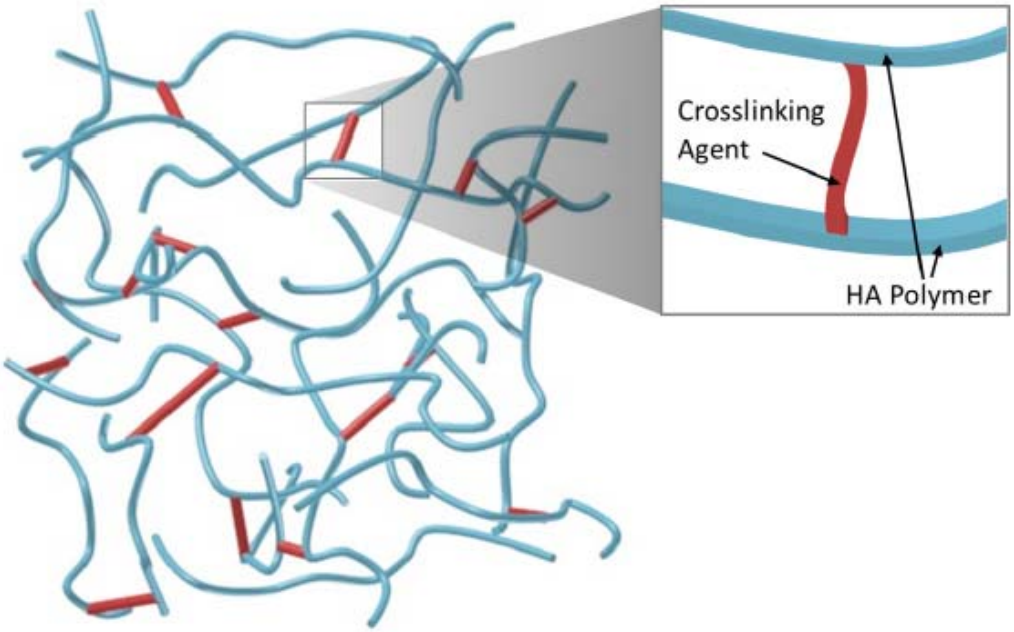
(Kablik 304.) "Whether chemical modification results in formation of a cross-link (a bond between two strands of HA) or a pendant group [a crosslinking agent bonded to only one strand of HA] is a function of the reaction conditions used by different manufacturers of HA fillers."

(Kablik 304.) The crosslinking agent, such as 1,4-butanediol diglycidal ether ("BDDE"), forms a covalent bond with the HA polymer chain:



(Tezel, Fig. 5 ("BDDE . . . crosslinking agent used to bind HA polymer chains to each other, transforming liquid HA solutions into gels. Both the primary hydroxyl site (-CH_2OH) and secondary hydroxyl sites (-CHOH) within the HA monomeric unit are possible target sites for reactions with BDDE.").)

A crosslinked HA gel can be visualized as follows:



(Pls.' Opening Claim Construction Br. 3.) Scientists and clinicians often use the "degree of crosslinking" as a measure of the hardness of a crosslinked HA gel, because as the number of crosslinkages increase, the gel's flexibility decreases. (Tezel 38.) The parties agree that "degree

of crosslinking" should be construed as "the percent weight ratio of crosslinking agent to HA monomeric units (HA disaccharide units) within the crosslinked portion of the HA based composition (i.e., (total mass of crosslinking agent / total mass of monomeric units) * 100))." (Jt. Claim Construction and Prehearing Statement 3.) This is slightly different from the literature definition, which is based on counts, not weights: "to say that a dermal filler has a degree of crosslinking of 4% means that, on average, there are four crosslinker molecules for every 100 disaccharide monomeric units of HA." (Tezel 38.)

Uncrosslinked HA is a liquid, but crosslinked HA is an insoluble gel that resists degradation. (Kablik 304-05; Tezel 36.) But crosslinked HA can be too viscous to inject into the skin through a fine gauge needle. ('475 Patent 2:7-14.) To make the crosslinked HA gel easier to inject, some manufacturers add liquid uncrosslinked HA as a soluble fluid component, helping the filler move through small needles. (Kablik 305; Tezel 39.) But because uncrosslinked HA degrades quickly, the appropriate balance must be struck between cross-linked HA and uncrosslinked HA. (Kablik 305.)

To mitigate injection discomfort, anaesthetic agents such as lidocaine are used. ('475 Patent 2:20-23.)

2. OVERVIEW OF THE '475 AND '795 PATENTS

The '475 Patent concerns HA-based soft tissue fillers that include at least one anesthetic agent. ('475 Patent 2:36-41.) The HA-based compositions described in the patent have "an enhanced stability, relative to conventional HA-based compositions including, for example, lidocaine, when subjected to high temperatures and pressures." ('475 Patent 5:32-38.) The '475 Patent claims compositions comprising (1) HA crosslinked with BDDE, (2) uncrosslinked HA, and (3) an anesthetic agent such as lidocaine. ('475 Patent 16:40-18:59.) The specifications describe the concentration of HA in the compositions as between about 10 mg/mL and 40 mg/mL. ('475 Patent 5:51-58.) The specifications also describe the concentration of lidocaine as between about 0.1% and about 5% by weight of the composition. ('475 Patent 6:13-16.)

An objective of the '475 Patent was to avoid the "partial or almost complete degradation prior to injection" that tended to occur in HA-based compositions that incorporated lidocaine. ('475 Patent 2:15-32.) The '475 Patent teaches that such compositions were especially prone to degradation "during high temperature sterilization steps and/or when placed in storage for any significant length of time." ('475 Patent 2:27-28.) The specifications describe sterilization as "any method known in the art to effectively kill or eliminate transmissible agents" and an important step in making the HA-based compositions. ('475 Patent 11:14-17.) Autoclaving is "[o]ne preferable method of sterilization of the filled syringes" that "can be accomplished by applying a mixture of heat, pressure and moisture to a sample in need of sterilization." ('475 Patent 11:18-21.) Disinfectant gas and irradiation can also be used to sterilize dermal fillers. (*See* '475 Patent 11:29-44.)

The '795 Patent also relates to HA-based soft tissue fillers that include at least one anesthetic agent. ('795 Patent 2:36-41.) The '795 Patent is very similar to the '475 Patent, but discloses another experimental example, and contains a different set of claims. ('795 Patent 15:21-17:2, 19:20-22:27.)

3. AGREED TERMS

The Parties agree upon the following constructions:

'475 Patent	
sterile (claims 1, 18, 27, 34)	substantially free of detectable, viable microorganisms
degree of crosslinking (claims 5-7, 18, 27, 31, 37)	the percent weight ratio of crosslinking agent to HA monomeric units (HA disaccharide units) within the crosslinked portion of the HA based composition (i.e., (total mass of crosslinking agent/ total mass of monomeric units)*100)) The "crosslinked portion of the HA based composition" as used herein has the same construction as the other terms referring to "crosslinked HA," as construed by the Court.

[X]% uncrosslinked HA by volume (claims 1, 2, 33, 36)	the percent weight ratio of uncrosslinked HA in a filler composition (i.e., ((mass of uncrosslinked HA in the composition/mass of total HA in the composition)*100) Uncrosslinked HA as used herein has the same construction as the "uncrosslinked HA" term, as construed by the Court.
[X]% free HA by volume (claim 27)	the percent weight ratio of free HA in a filler composition (i.e., ((mass of free HA in the composition / mass of total HA in the composition)*100) Free HA as used herein has the same construction as the "free HA" term, as construed by the Court.
'795 Patent	
sterile (claim 1)	substantially free of detectable, viable microorganisms
lidocaine is freely released in vivo (claim 1)	plain and ordinary meaning
extrusion force (claim 41)	the force that one must apply to expel a soft tissue filler composition through the needle in its assembled, intended delivery system

(Jt. Claim Construction and Prehearing Statement, Dkt. No. 52.) These constructions will bind the parties. *See MyMail, Ltd. v. Am. Online, Inc.*, 476 F.3d 1372, 1377-78 (Fed. Cir. 2007) (rejecting appellate challenge to claim construction agreed to by party in district court). But the Court makes one change. *Ceteris paribus* (other things being equal), the Court prefers to give the jury claim constructions in English. So, while a person of ordinary skill in the art would readily understand the Latin term "in vivo," the Court construes "lidocaine is freely released in vivo" to mean "lidocaine is freely released in a patient's body."

4. CONSTRUCTION OF THE DISPUTED TERMS

4.1 "stable"

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
stable ('475 Patent claims 1, 18, 27, 31, 34)	resists chemical and physical decomposition	A sterile composition that maintains one of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration, after being stored at about 25C for about two months

'475 Patent claim 1 is reproduced here for context with the disputed term in bold:

> 1. A **stable**, sterile soft tissue filler comprising:
>
> a hyaluronic acid (HA) component comprising HA crosslinked with 1,4 butanediol diglycidyl ether (BDDE), and uncrosslinked HA, wherein the HA component comprises greater than about 10% uncrosslinked HA by volume, and
>
> lidocaine combined with said crosslinked component.

('475 Patent 16:40-46.)

Defendants agreed in their responsive brief to drop their request that the construction include the term "sterile composition," the 25ºC storage temperature, and the two-month storage period. (Defs.' Answering Claim Construction Br. 3.) The resulting proposed construction is "maintains one of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration." (S.P.R. 3.5.1 Chart of Proposed Constructions.)

Defendants argue that their construction relies on the definition of "stable" in the '475 Patent, which Defendants argue is used throughout the patent to measure stability. (Defs.' Opening Claim Construction Br. 7-8.) But Plaintiffs respond that Defendants' proposal comes from the '475 Patent's definition of "autoclave stable," and that the more general term, "stable," should not be so limited. (Pls.' Opening Claim Construction Br. 7-11.)

While Plaintiffs argue that a person of ordinary skill in the art would understand their construction to be the plain and ordinary meaning of "stable," they only support this argument with two dictionary definitions. (*See* Pls.' Opening Claim Construction Br. 7-8.) Such "heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract." *Phillips*, 415 F.3d at 1321.

To link their construction to the intrinsic record, Plaintiffs point to passages in the '475 Patent discussing the conditions under which the compositions should be stable. (Pls.' Opening Claim Construction Br. 8.) These passages do use "stable" without reciting the list of metrics that appears elsewhere in the specification, but they do not specifically address the meaning of the term. (*See* '475 Patent 2:7-17; 2:42-48.) Nothing in the specification suggests that "stable" carries a meaning divorced from the specific metrics discussed, and "[t]he claims of a patent are always to be read or interpreted in light of its specifications." *Phillips*, 415 F.3d at 1316 (quoting *Schriber–Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 217 (1940).)

Nor, as Plaintiffs argue, does the absence of discussion about the term in the prosecution history support a dictionary-based construction. (Pls.' Opening Claim Construction Br. 9-10.) While the prosecution history does not contain a disclaimer of the scope of the term, it also contains nothing showing that the applicant or examiner understood the term to be as broad as Plaintiff's proposed definition.

Because it lacks a standard for measuring resistance to physical and chemical decomposition, Plaintiffs' construction would frustrate a comparison of the patented invention to the allegedly infringing invention. "Courts construe claim terms in order to assign a fixed,

unambiguous, legally operative meaning to the claim." *Chimie v. PPG Industries, Inc*., 402 F.3d 1371, 1377 (Fed. Cir. 2005). Plaintiff's construction is too vague to provide such a meaning.

And, contrary to Plaintiffs' argument, Defendants' construction is not solely based on the patent's definition of "autoclave stable." The specification lists ways to measure the stability of the disclosed compositions: "The stable compositions maintain at least one of, or all of, the following aspects after effective autoclave sterilization **and/or** prolonged storage: transparent appearance, pH for use in a patient, extrusion force and/or rheological characteristics, HA concentration, sterility, osmolarity, and lidocaine concentration." ('475 Patent 5:39-44 (emphasis added).)

These metrics were not limited to stability during autoclaving. The specification again lists measures of stability that apply in circumstances beyond autoclaving: "the compositions maintain their integrity in terms of rheology, viscosity, appearance and other characteristics **even when stored for a lengthy period of time** . . . and even after being subjected to sterilization procedures, **for example**, autoclaving." ('475 Patent 6:49-54 (emphasis added).) These measures of stability apply to both sterilization and storage, thus linking Defendants' construction to all the disclosed types of stability.

Defendants' construction thus appropriately walks the "fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Phillips*, 415 F.3d at 1323 (quoting *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186–87 (Fed. Cir. 1998).) But Defendants' construction says "one of" rather than "at least one of" as in the specification, and Defendant did not explain the change. The Court will therefore use the "at lease one of" language. Defendants' construction, as thus modified, "stays true to the claim language and most naturally aligns with the patent's description of the invention," *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

The Court therefore construes "stable" as "maintains at least one of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration."

4.2 The "Crosslinked HA" Terms

Term(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
HA crosslinked with 1, 4-butanediol diglycidyl ether (BDDE) ('475 Patent claims 1, 31, 34) hyaluronic acid (HA) component crosslinked with 1, 4 butanediol diglycidyl ether (BDDE) ('475 Patent claim 18) (BDDE)-crosslinked hyaluronic acid ('475 Patent claim 27)	HA that forms a macromolecular structure resulting from chemical linking of HA by BDDE	HA that has been covalently modified with BDDE to form a macromolecular structure that is water-insoluble, such that the degree of crosslinking is at least about 2% and is up to about 20%
hyaluronic acid (HA) component crosslinked with a crosslinking agent ('795 Patent claim 1)	HA that forms a macromolecular structure resulting from chemical linking of HA by a crosslinking agent	HA that has been covalently modified with a crosslinking agent to form a macromolecular structure that is water-insoluble, such that the degree of crosslinking is at least about 2% and is up to about 20%

The only difference between the '475 Patent crosslinked-HA terms and the '795 Patent crosslinked-HA term is that the '475 Patent's claims specify BDDE as the crosslinking agent. The parties dispute (1) whether "chemical" or "covalently" should describe the bond formed by the crosslinking agent, (2) whether "linking" or "modified" should describe how HA and the crosslinking agent form a macromolecular structure, (3) whether "water-insoluble" needs to be included, and (4) whether the "degree of crosslinking" needs to be included.

4.2.1 "Chemical" vs. "Covalent"

Plaintiffs argue that "the plain meaning of 'crosslink' suggests that one material—a crosslinking agent—chemically connects two materials together." (Pls.' Opening Claim Construction Br. 13-14.) Plaintiffs cite the Random House Dictionary definition of "crosslink":

"a bond, atom, or group linking the chains of atoms in a polymer or other complex organic molecule." (*Id.*) Defendants argue that "covalently modified" more accurately describes the cross linkages and that Plaintiffs' construction is too broad and vague. (Defs.' Opening Claim Construction Br. 9.) Plaintiffs do not contest that the linkages connecting the HA strands to the BDDE molecules are covalent bonds. (Pls.' Opening Claim Construction Br. 15, "[c]rosslinking agents are capable of forming two covalent bonds with HA.") But Plaintiffs argue that using the technically accurate term "covalent" to describe the cross linkages will confuse the fact-finder. (Pls.' Responsive Claim Construction Br. 3.)

The specter of confusion is no excuse for imprecision. Chemical bonds include ionic bonds and covalent bonds. Volhardt and Schore, *Organic Chemistry* 7 (1997). An article Plaintiffs submitted with their briefs states: "[a] gel with a lower number of cross-links **(covalent bonds)** has a greater length of the HA molecule between links." (Kablik 306 (emphasis added).) The same article specifically distinguishes between gels held together by (covalent) cross-linking and those more weakly held together by hydrogen bonding: "The HA modified with predominantly pendant groups forms gels that are held together by physical entanglement due to interchain hydrogen bonding. These gels are not as strong as the ones produced by creating a covalently cross-linked network." (Kablik 310.)

Thus, including "covalently" in the construction would give an appropriate level of precision to "resolve disputed meanings and technical scope in order to aid the fact-finder." *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.* 528 F. Supp. 2d 967, 982 (Fed. Cir. 2009) (citing *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997)). The Court therefore includes "covalently" in the construction.

4.2.2 "Linking" vs. "Modified"

Defendants' proposed construction omits an important concept by using "modified" in place of Plaintiffs' "linked." To be cross-linked, HA is not just **modified** with crosslinkers to create modified but unlinked HA. To the contrary, crosslinked HA has "intermolecular

junctions **joining** the individual HA polymer molecules, or monomer chains, into a permanent structure." ('475 Patent 4:62-65; '795 Patent 5:43-46 (emphasis added).) If the cross-linking agent bonds only on one of its ends, connecting to only one strand of HA, the HA polymer molecules are not joined. (*See* Kablik 304.) Defendants' construction does not require the cross-linking agent to connect to HA strands on both ends, thus allowing modification without cross-linkage. Defendants argue that the rest of its construction—"to form a macromolecular structure that is water-insoluble"—precludes such an interpretation. (Defs.' Answering Claim Construction Br. 4). But there is no reason to introduce the ambiguity, just as ambiguity should be avoided on the chemical vs. covalent issue.

"Linking" from Plaintiffs' construction is consistent with the patents' use of "crosslinked HA" and avoids describing modified but unlinked HA. The Court therefore includes "linking" in the construction.

4.2.3 "Water Insoluble"

Plaintiffs argue that there is no basis in the intrinsic record to construe "crosslinked HA" as "water insoluble," but offer no evidence supporting the idea that crosslinked HA is water soluble. (Pls.' Opening Claim Construction Br. 16.) And the prior art cited in the patents confirms that crosslinked HA is water insoluble. (*See, e.g.*, Cavanaugh Decl., Dkt. No. 54-4, Ex. 4, U.S. Patent No. 8,124,120 1:20-23; 2:6-8.) "[P]rior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence." *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011) (citations omitted).

The specifications of both patents also support construing "crosslinked HA" as "water insoluble." (*See, e.g.*, '475 Patent 3:65-67, 7:4-9, 7:29-35, 9:49-54, 12:37-39, 13:9-11; '795 Patent 3:66-4:1.) Nothing in the specifications suggests that crosslinked HA is water soluble. The extrinsic evidence cited by Plaintiffs also supports the notion that crosslinked HA is water insoluble: "Thus, a network of cross-linked HA retains its structure until sufficient degradation has occurred at the gel surface to form soluble oligosaccharides that can be metabolized and

cleared from the body" (Kablik 304); "The total HA concentration consists of insoluble HA gel and soluble-free HA." (Kablik 305.)

Further, failing to include "water insoluble" in the construction could allow lightly crosslinked HA, which the parties and both patents classify as free or uncrosslinked HA, to be classified as "crosslinked HA" as well. (*See* '475 Patent 3:10-13, 5:5-13; '795 Patent 5:53-61.) The extrinsic evidence also suggests that would be inaccurate:

> This fluid component contains unmodified and modified soluble HA that is generated during the manufacturing process when HA fragments are formed as a side-product of the chemical modification. These soluble fluids are easily metabolized and do not contribute to the extended duration and effectiveness of the product. Only the cross-linked HA resists enzymatic and radical degradation and therefore extends the filler's presence in the dermis, contributing to its effectiveness.

(Kablik 305.) The Court therefore includes "water-insoluble" in the construction to prevent overlap with "uncrosslinked HA."

4.2.4 "Degree of Crosslinking Between 2% and 20%"

Defendants' construction requires the degree of crosslinking to be between 2% and 20%. The specification states that "[t]he degree of crosslinking in the HA component of the present compositions is at least about 2% and is up to about 20%." ('475 Patent 9:31-33.) The question is whether this reference to "the present compositions" is enough to limit the claims, or whether that language merely refers to nonlimiting preferred embodiments.

> It is true that, in some circumstances, a patentee's consistent reference to a certain limitation or a preferred embodiment as 'this invention' or the 'present invention'

> can serve to limit the scope of the entire invention, particularly where no other intrinsic evidence suggests otherwise. . . . On the other hand, we have found that use of the phrase 'present invention' or 'this invention' is not always so limiting, such as where the references to a certain limitation as being the 'invention' are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent.

Absolute Software, Inc. v. Stealth Signal, Inc., 659 F.3d 1121, 1136-37 (Fed. Cir. 2011) (citing *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007)); *see also Voda v. Cordis Corp.*, 536 F.3d 1311, 1320–22 (Fed. Cir. 2008) (declining to import the limitation where parts of the specification referred to a certain embodiment as the "present invention," but the specification did not uniformly refer to the invention as being so limited, and the prosecution history did not reveal such a limitation).

While the Court ultimately reaches the contrary conclusion, the 2%-20% statement is given in a context that suggests that it relates to the "invention," and not just a preferred embodiment:

> Degree of crosslinking **for purposes of the present disclosure** is defined as the percent weight ratio of the crosslinking agent to HA-monomeric units within the crosslinked portion of the HA based composition. It is measured by the weight ratio of HA monomers to crosslinker (HA monomers: crosslinker).
>
> The degree of crosslinking in the HA component **of the present compositions** is at least about 2% and is up to about 20%.
>
> In some embodiments, the degree of crosslinking is between about 4% to about 12%. In some embodiments, the degree of crosslinking is less than about 6%, for example, is less than about 5%.
>
> In other embodiments, the degree of crosslinking is greater than 5%, for example, is about 6% to about 8%.

('475 Patent 9:25-39 (emphasis added).) Thus, the specification introduces the 2%-20% range immediately after providing a definition that applies to all claims, using "the present compositions" language, and then proceeds to give more specific examples within the 2%-20% range.

But the specification never again refers to a 2%-20% limitation. (*See* '475 Patent.) Also, the patent itself uses phrases such as "the present compositions" and "present description" in a slightly inconsistent manner, at times using "the present description" to refer to what is clearly only an example. (*See* '475 Patent 14:30-36.) The specification therefore does not show a uniform intention to limit the invention to a degree of crosslinking of about 2%-20%. (*See* '475 Patent 9:34-45.) Claims 5, 6, and 7 require the HA component to have a degree of crosslinking less than about 6%, less than about 5%, and about 2%, respectively. (*See* '475 Patent 16:56-61.) Some claims containing the "crosslinked HA" terms do not specify a numerical value for the degree of crosslinking, merely claiming "HA crosslinked with . . . (BDDE)." (*See* '475 Patent Claims 1, 34.)

"[W]hen a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." *Renishaw*, 158 F.3d at 1249; *see also Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1357–58 (Fed. Cir. 2006). And, independent Claim 27 expressly requires a degree of crosslinking of "about 2% to about 20%." ('475 Patent 18:16-18.) Defendants' proposed limitation would render that language superfluous. While "[c]laim differentiation is a guide, not a rigid rule," because differently worded claims can define the exact same subject matter, "claim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1381 (Fed. Cir. 2006).

Further, the prosecution history contains no suggestion that the 2% to 20% range was included in the specification in order to avoid prior art. (*See* Certified File History for U.S. Patent No. 8,450,475, 2011-05-31 Non-Final Rejection; 2011-11-09 Amendment/Req. Reconsideration After Non-Final Rejection; 2012-02-03 Non-Final Rejection; 2012-07-30

Amendment/Req. Reconsideration After Non-Final Rejection; 2012-11-19 Final Rejection; 2013-02-06 Office Action Appendix; 2013-02-19 Amendment Submitted/Entered with Filing of CPA/RCE; 2013-03-25 Amendment After Final or under 37 CFR 1.312, 2013-04-18 Amendment After Notice of Allowance (Rule 312); 2013-04-29 Amendment After Final or under 37 CFR 1.312; 2013-04-29 Notice of Allowance and Fees; 2013-05-03 Amendments to Specification.) And, the Patent Office allowed the final version of claims 5 and 6, which claim a "degree of crosslinking of less than about 6%" and "less than about 5%," respectively, with no lower bound on the degree of crosslinking. (*See id.*, '475 Patent 16:56-59.)

While the specification does mention a 2%-20% crosslinking range, neither the specification nor the prosecution history contain a clear disclaimer of other ranges, and importing that limitation into the claims would render language in Claim 27 superfluous. Therefore, the Court does not include "such that the degree of crosslinking is at least about 2% and is up to about 20%" in the construction.

4.2.5 Conclusion

For the reasons discussed in Sections 4.2.1 through 4.2.4, the Court construes the "crosslinked HA" terms in the '475 Patent as "HA that forms a water-insoluble macromolecular structure resulting from covalent linking of HA by BDDE," and in the '795 Patent as "HA that forms a water-insoluble macromolecular structure resulting from covalent linking of HA by a cross-linking agent."

4.3 "Uncrosslinked HA" and "Free HA"

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
uncrosslinked HA; free HA ('475 Patent claims 1, 2, 4, 9, 18, 27, 28, 29, 31, 33, 34, 36)	water soluble HA (i.e., uncrosslinked HA and/or lightly crosslinked HA)	water soluble HA (i.e., uncrosslinked HA and/or lightly crosslinked HA) that is added to the crosslinked HA portion of the composition

The parties dispute whether the term should be limited to uncrosslinked HA that is added after the BDDE has reacted with the HA to create crosslinked HA. Plaintiffs argue that the source of the uncrosslinked HA in the composition is irrelevant because the claims in question are composition claims, not product-by-process claims. (Pls.' Opening Claim Construction Br. 19.) Defendants argue that the patentees disclaimed any uncrosslinked HA that is not added to the already crosslinked HA during prosecution to avoid prior art. (Defs.' Opening Claim Construction Br. 14-18.)

The parties correctly agree that the construction should include at least "water soluble HA (i.e. uncrosslinked HA and/or lightly crosslinked HA)." The specifications teach that "[f]ree HA as used herein refers to individual HA polymer molecules that are not crosslinked to, or very lightly crosslinked to (very low degree of crosslinking) the highly crosslinked (high degree of crosslinking) macromolecular structure making up the soft tissue filler of the composition. Free HA generally remains water soluble." ('475 Patent 5:5-10.)

Defendants argue that the '475 Patent applicant disclaimed compositions containing uncrosslinked HA remaining after the crosslinking process, and instead, only claimed compositions in which uncrosslinked HA was added after a crosslinking process that linked all of the HA. (Defs.' Opening Claim Construction Br. 16.) Defendants point to the applicant's argument, made to overcome a prior art-based rejection, that "there is no reason to believe that Lebreton's [a prior art's] compositions would have any uncrosslinked HA." (Defs.' Opening Claim Construction Br. 16 (quoting Nov. 9, 2011 Response to Office Action, Dkt. No. 54-7).)

The doctrine of prosecution history disclaimer applies "where the patentee has unequivocally disavowed a certain meaning to obtain his patent," but not "where the alleged disavowal of claim scope is ambiguous." *Omega Engineering, Inc, v. Raytek Corp*., 334 F.3d 1314, 1324 (Fed. Cir. 2003). In its Response to Office Action, the applicant stated only that there would be no uncrosslinked HA after the crosslinking process in the prior art's HA-based composition with 6.5% crosslinking, because at 6.5% crosslinking, each HA molecule would have an average of 250 linkages. (Cavanaugh Decl., Ex. 7 ("Response to Office Action") at 11-12 (correcting examiner's reasoning that with 6.5% crosslinking, 93.5% of HA would be uncrosslinked, because % crosslinking and % of HA molecules that are crosslinked are different measures).)

In so distinguishing the prior art, the applicant did not argue that the claimed compositions in the '475 Patent would have no uncrosslinked HA after the crosslinking process. (*See* Response to Office Action at 11-12.) On the contrary, the specifications allow for uncrosslinked HA as a remnant of the crosslinking process. ('475 Patent 5:14-21 ("Cohesiveness is affected by . . . the amount of residual free HA following crosslinking") *see also* '475 Patent 6:23-34.)

Both the Kablik and Tezel articles also support the possibility of uncrosslinked HA being present in the composition after the crosslinking process. (Kablik 305 ("Although not all manufacturers add HA fluid to their fillers, a fluid component is often present. This fluid component contains unmodified and modified soluble HA that is generated during the manufacturing process when HA fragments are formed as a side-product of the chemical modification"); Tezel 39 ("some manufacturers of dermal fillers *add/use* uncrosslinked HA as a lubricant.") (emphasis added).)

The prosecution history does not show a "clear and unmistakable disclaimer" of uncrosslinked HA present in the crosslinked HA composition as a byproduct of the manufacturing process. *Cordis Corp. v. Boston Scientific Corp*., 561 F.3d 1319, 1329 (Fed. Cir. 2009) (quoting *Free Motion Fitness, Inc. v. Cybex Int'l, Inc*., 423 F.3d 1343, 1353 (Fed. Cir. 2005)). In the cited Lebreton prior art, United States Patent Application Publication

2006/0194758 (Aug. 1, 2006), the approach to generating a gel of the desired injectability was to crosslink low molecular weight polymers with high molecular weight polymers. (Dkt. No. 54-6 ¶¶ 21, 46-50.) The applicant argued during prosecution that there was no uncrosslinked HA after the crosslinking process in the Lebreton prior art, but did not disclaim the specification's teaching that there could be uncrosslinked HA after the crosslinking step in the '475 and '795 Patents.

Further, most of the claims containing the terms "uncrosslinked HA" and "free HA" are composition claims, not product-by-process or method claims. Composition claims are not limited by manufacturing methods. *See, e.g.*, *Vanguard Products Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) (noting that a "novel product that meets the criteria of patentability is not limited to the process by which it was made"). By requiring uncrosslinked HA to be "added to the crosslinked HA portion of the composition," Defendants' construction would add method of manufacture steps to the composition claims. Further, this construction would add a manufacturing step not required by the patent because the specifications allow, but do not require, uncrosslinked HA to be added to the crosslinked HA. (*See, e.g.*, '475 Patent 13:9-11.) So, Defendants' construction would improperly import an expressly optional portion of the specifications into the claims. *See Phillips*, 415 F.3d at 1323 (courts should "avoid the danger of reading limitations from the specification into the claim").

The Court therefore rejects Defendants' construction and construes "uncrosslinked HA" and "free HA" as "water soluble HA (i.e., uncrosslinked HA and/or lightly crosslinked HA)."

DISPOSITION

These claim constructions shall govern this case.

IT IS SO ORDERED.

DATED: August 12, 2014

Andrew J. Guilford
United States District Judge